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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,757	09/24/2003	Alan Klotz	10211.200-US	4235

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NOVOZYMES, INC.
1445 DREW AVE
DAVIS, CA 95616

EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,757	KLOTZ ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,60,61,130,133,138-140 and 143-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,60,61,130,133,138-140 and 143-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *September 24, 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

Applicant's request for continuing examination filed November 30, 2006, in response to the Final Rejection mailed February 17, 2006 and the Advisor Action mailed September 26, 2006, is acknowledged. It is acknowledged that Claims 134-137, 141, and 142 have been cancelled and Claims 1, 138, and 143 have been amended. Claims 1, 60, 61, 130, 133, 138-140, 143-145 are pending and are hereby reconsidered.

Priority

The priority date for the instant invention is taken to be September 24, 2003, the filing date of the instant application. Provisional Application 60/413,057, filed September 24, 2003, fails to disclose chymotrypsin variants, wherein the positions corresponding to positions 144, 193, 198, 201, 218, 223, 227, 228, 229, 230, and 231 of SEQ ID NO: 2 have been substituted with all possible amino acid residues.

Drawings

Objection to Figure 3 for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:), as explained in the prior action, is maintained. Correction is required.

Specification

The specification is objected to because the legend to Figure 3 states that a gene is disclosed in said figure. There are only proteins disclosed in Figure 3; no genes or

polynucleotides are disclosed therein.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claims 1, 60, 61, 130, 133, 138-140, 143-145 under 35 U.S.C. 112, second paragraph, as being rendered indefinite by the phrase "microbial trypsin", as explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. The specification teaches that the microbial trypsin may be a naturally occurring (wild-type) polypeptide or it may be a variant thereof (pg 4-5). Applicants use the term "microbial trypsin" throughout the specification and the skilled artisan would clearly understand that a microbial trypsin is obtained from a microbial source such as F. oxysporum. Such a microbial trypsin may be a naturally occurring, wild-type, or a variant thereof.

These arguments are not found to be persuasive for the following reasons. The specification fails to formally define the phrase "microbial trypsin". The skilled artisan would assume that said phrase encompasses only enzymes expressed by a microbial cell. Applicants' assertion that "microbial trypsin" also encompasses any variant of any naturally occurring enzyme renders the claims indefinite. For purposes of clarity, it is suggested that the phrase "microbial trypsin" on Claim 1, line 9, as well as Claims 138-140, and 143-145, line 1 for each, be amended to "trypsin polypeptide".

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1, 61, 130, 133, 138-140, 143-145 under 35 U.S.C. 112, first paragraph, lack of enablement, for the reasons set forth in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The Office asserts that the recited invention would require undue experimentation because the encompassed genus of "microbial trypsin" polypeptides is extremely large and that all microbial trypsins could not be aligned with SEQ ID NO: 2. Applicants disagree. The claims have been amended such that the microbial trypsin polypeptide has at least 90% homology to SEQ ID NO: 2 or is encoded by a polypeptide that hybridizes under medium-high stringency.

(B) The issue is whether, in an unpredictable art, 35 USC 112 requires the inventor to test "hundreds" of variants, which would be prohibitive. Applicants' invention is not complicated; the experimentation is routine. Guidance for construction of variants with chymotrypsin-like activity is given in both the specification and the prior art. The mere fact that experimentation may be time-consuming does not mandate that such experimentation is undue.

(A) Reply: It is acknowledged that the claims have been amended such that the trypsin polypeptide has at least 90% homology to residues 25-248 of SEQ ID NO: 2 or is encoded by a polypeptide that hybridizes under medium-high stringency with residues 202-801 of SEQ ID NO: 1. Said amendment dramatically reduces the genus of trypsin polypeptides used

as "parent" molecules for making the recited variants having chymotrypsin activity. The skilled artisan would be enabled for identifying said genus of trypsin polypeptides. Therefore, this basis of the rejection is withdrawn.

(B) Reply: It is acknowledged that the principle question under 35 USC 112 is whether undue experimentation is required to practice the invention. As per *In re Wands*, the factors used to answer said question includes the breath of the claims. The instant invention encompasses any variant polypeptide having any structure and having chymotrypsin activity. It is acknowledged that the genus of parent trypsin molecule is limited to those having at least 90% homology to residues 25-248 of SEQ ID NO: 2 or is encoded by a polypeptide that hybridizes under medium-high stringency with residues 202-801 of SEQ ID NO: 1. It is also acknowledged that the recited variants are derived from said parent trypsin polypeptide wherein, 12 specific positions analogous to SEQ ID NO: 2 have been substituted, 3 specific positions analogous to SEQ ID NO: 2 have been deleted, and there is any insertion between the two positions analogous to 224 and 225 of SEQ ID NO: 2. However, these structural limitations describe the parent polypeptide; the claims fail to provide any structural limitation for the recited genus of variant polypeptides having chymotrypsin activity. It is acknowledged that Applicants' invention is not complicated and that the experimentation is routine. However, clearly, neither the specification nor the prior art provide sufficient guidance to enable the skilled artisan to make all polypeptides having chymotrypsin activity.

Written Description

Claims 1, 61, 130, 133, 138-140, 143-145 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of variant protein molecules having chymotrypsin activity. The specification teaches the structure of only a single representative species of such proteins. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having chymotrypsin activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 61, 133, 138-140, 143-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartley et al, 1964. Hartley et al teach a chymotrypsin polypeptide having (a) substitutions at positions corresponding to positions 144, 193, 198, 201, 218, 223, 227, 228, 229, 230, and 231 of SEQ ID NO: 2, (b) deletion at positions corresponding to positions 192, 197, and 226 of SEQ ID NO: 2, and (c) an insertion between positions corresponding to positions 224 and 225 of SEQ ID NO: 2 (see enclosed alignment). Therefore, Claims 1, 61, 133, 138-140, 143-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartley et al, 1964.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 130 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al, 1994 in view of Hames et al, 1990. The teachings of Hartley et al are described above. Hartley et al do not teach their chymotrypsin protein in a detergent solution. Hames et al teach a method for performing gel electrophoretic separation of proteins denatured by the detergent SDS (SDS-PAGE). It would have been obvious to a person of ordinary skill in the art to use the method of Hames et al to prepare analyze the protein of Hartley et al by SDS-PAGE. Motivation to do so derived from the desire to determine the purity of a recombinant preparation of the protein of Hartley et al. The expectation of success is high, as SDS-PAGE is standard in the art. Therefore, Claim 130 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al, 1994 in view of Hames et al, 1990.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1652